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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,642	06/18/2001	Denisa D. Wagner	CFBF-P02-004	3076

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	14

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/883642	Applicant(s) WAGNER
	Examiner GAMBEL	Art Unit 644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/5/03

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application. 39-52, 61-68, 71-74, 76-79, 83, 87

4a) Of the above claim(s) _____ is/are withdrawn from consideratio 69, 83, 87

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected. 39-52, 61-69, 71-74, 76-79,

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requireme

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disappr d by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

PAPER NO. 14

DETAILED ACTION

1. Applicant's amendment, filed 5/5/03 (Paper No. 13), has been entered.
Claims 53-60, 70, 75, 80-82, 84-86 and 88 have been canceled.
Claims 1-38 have been canceled previously.

Claims 39, 40, 61-65, 69, 71-74 and 76-79 have been amended.

Claims 39-52, 61-69, 71-74, 76-79, 83 and 87 are pending.

Claims 39-52, 61-68, 71-74 and 76-79 are being acted upon as the elected invention.

Claims 69, 83 and 87 has been withdrawn as being drawn the non-elected inventions.

For examination purposes, it is noted that it has been known in the art that PADGEM, GMP-140 and P-selectin are all the same molecule, that is, CD62P.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 5/5/03 (Paper No. 13).
The rejections of record can be found in the previous Office Actions (Paper No. 11).

3. Applicant is invited to carefully review the pertinent identifying data on correspondence sent to the USPTO.

The instant USSN is "09/883,642" and not "08/948,393", as indicated on Applicant's amendment, filed 5/5/03 (Paper No. 13).

4. Applicant should amend the first line of the specification to disclose the correct information about the priority documents of the instant application.

USSN 08/253,663 was filed 6/3/94 and not 5/3/94, as currently disclosed.

7. Applicant's amendment, filed 5/5/03 (Paper No. 13), has obviated the previous rejection under 35 U.S.C. § 112, second paragraph, with respect to the recitation of "at least partially" "inhibit" or "reverse"

8. Claims 39, 42-52, 61-65, 68, 74 and 76-79 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Furie et al. (EP 0496832) (1449; #AQ) (see entire document) essentially for the reasons of record.

Applicant's arguments, filed 5/5/03 (Paper No. 13), have been fully considered but are not found convincing essentially for the reasons of record set forth in Paper No. 11.

Applicant argues that Furie et al. does not disclose that P-selectin-specific antibodies can be used to inhibit the interaction of both P-selectin, and E-selectin and a ligand of E-selectin or L-selectin and a ligand of L-selectin as required by the present claims.

As pointed out previously, Furie et al. teach methods of treating PADGEM-mediated events, including those associated with platelets, leukocytes and endothelial cells, in various processes, including atherosclerosis, clotting and inflammation, including the use of anti-PADGEM antibodies (e.g., see entire document, including the Description on columns 1-2 and Claims).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed anti-P-selectin antibody, the effects on atherosclerotic lesions (e.g. see claim 62-65) would be inherent properties of the referenced methods of treating atherosclerosis with anti-PADGEM antibodies.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Also, see Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Applicant has not distinguished the prior art teaching from employing the same inhibitory anti-P-selectin antibody to inhibit the same atherosclerosis encompassed by the claimed invention.

The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Even though applicant has proposed or claimed the mechanism(s) by which the anti-P-selectin antibody treats or inhibits atherosclerosis, the claims do not appear to be distinguished the prior art teaching the same or nearly the same methods with the same agents to achieve the same end result. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Also see Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) which states: "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Applicant's arguments are not found persuasive for the reasons of record.

9. Claims 39-52, 61-68, 71-74 and 76 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Palabrica et al. (WO 93/06863) (1449; #AU) (see entire document) for the reasons of record.

Applicant's arguments, filed 5/5/03 (Paper No. 13), have been fully considered but are not found convincing essentially for the reasons of record set forth in Paper No. 11.

Applicant argues that Palabrica et al. does not disclose that P-selectin-specific antibodies can be used to inhibit the interaction of both P-selectin, E-selectin and L-selectin binding with their respective ligands.

As pointed out previously, applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claim 61), the effects on atherosclerotic lesions (e.g. see claims 62-65) would be inherent properties of the referenced methods of inhibiting vascular narrowing in a number of cardiovascular procedures, including those associated with atherosclerosis with anti-PADGEM antibodies. Palabrica et al. teach known dosages and modes of administration, including prior to, during and following cardiovascular surgery, as well as factors routinely considered by the attending physician (see pages 13-14, overlapping paragraph to page 14, paragraph 2).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Also, see Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Applicant is addressed to the examiner's rebuttal set forth above in Section 8 with respect to mechanisms of actions and properties associated with treating the same condition with the same agent to achieve the same therapeutic endresults.

Applicant's arguments are not found persuasive for the reasons of record.

10. Claims 39-52, 61-65, 68 and 73-74 stand rejected under 35 U.S.C. § 102 (a)(e) as being anticipated by McEver et al. (U.S. Patent No. 5,378,464) (see entire document) for the reasons set forth in the previous Office Action.

Applicant's arguments, filed 5/5/03 (Paper No. 13), have been fully considered but are not found convincing essentially for the reasons of record set forth in Paper No. 11.

Applicant argues that McEver et al. does not disclose that P-selectin-specific antibodies can be used to inhibit the interaction of both P-selectin, and E-selectin and a ligand of E-selectin or L-selectin and a ligand of L-selectin as required by the present claims.

Applicant also argues that McEver et al. describe a method for modulating an inflammatory response in a patient, such as circulatory shock, organ transplant rejection, myocardial infarction and ARDS by treating the patient with inhibitors for GMP-140, such as GMP-140-specific antibodies. Applicant argues that atherosclerosis is not an inflammatory disease as that term is used in the McEver et al. reference.

As pointed out previously, McEver et al. teach methods of inhibiting inflammatory responses, including those associated with ischemia and reperfusion, coagulation and atherosclerosis with effective amounts anti-GMP-140 antibodies that inhibiting GMP-140-mediated binding and adhesion and subsequent tissue damage(see entire document, particularly Diagnosis and Treatment of Disorders of the Inflammatory Response System on columns 20-23). McEver et al. acknowledge the well known use of thrombolytic agents at the time the invention was made (see column 20, paragraph 5).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention.

The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claim 61), the effects on atherosclerotic lesions (e.g. see claim 62-65) would be inherent properties of the referenced methods of inhibiting atherosclerosis with anti-GMP-140 antibodies.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Also, see Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Applicant is addressed to the examiner's rebuttal set forth above in Section 8 with respect to mechanisms of actions and properties associated with treating the same condition with the same agent to achieve the same therapeutic endresults.

Applicant's arguments are not found persuasive for the reasons of record.

11. Claims 39-52, 61-68, 71-74 and 76-79 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Furie et al. (EP 0496832) (1449; #AQ) AND/OR Palabrica et al. (WO 93/06863) (1449; #AU) AND/OR McEver et al. (U.S. Patent No. 5,378,464) in view of the art known use of combination therapies in the treatment of atherosclerosis, as taught by Coller et al. (U.S. Patent No. 5,976,532) (1449; #AO) in view of the art known underlying lesions of atherosclerosis and known treatments of atherosclerosis as acknowledged in the Background of the Invention on pages 1-2 of the instant specification and in view of the art known modes of administration practiced by the ordinary artisan at the time the invention was made, as acknowledged on pages 12-16 of the instant specification for the reasons set forth in the previous Office Action.

Applicant's arguments, filed 5/5/03 (Paper No. 13), have been fully considered but are not found convincing essentially for the reasons of record set forth in Paper No. 11.

Applicant arguments and the examiner's rebuttal are essentially the same as above with respect to the underlying mechanisms of the claimed invention with respect to the teachings of Furie et al., Palabrica et al. and Furie et al.

Applicant argues that the deficiencies of the primary references with respect to the inhibition of P-selectin, E-selectin and L-selectin and their ligands with anti-P-selectin antibodies is not cured by the teachings of Coller et al.

The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claim-61), the effects on atherosclerotic lesions (e.g. see claim 62-65) would be intrinsic or expected properties of the referenced methods of treating atherosclerosis with anti-PADGEM antibodies.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosures of Furie et al., Palabrica et al. And McEver et al.

Furie et al., Palabrica et al. And McEver et al. each differ from the claimed methods in differences in

Applicant is addressed to the examiner's rebuttal set forth above in Section 8 with respect to mechanisms of actions and properties associated with treating the same condition with the same agent to achieve the same therapeutic endresults.

Applicant's arguments are not found persuasive for the reasons of record.

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
July 17, 2003